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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/612,914	07/10/2000	Nabil Hanna	012712-905	9512

21839 7590 12/12/2001

BURNS DOANE SWECKER & MATHIS L L P
POST OFFICE BOX 1404
ALEXANDRIA, VA 22313-1404

EXAMINER	
BANSAL, GEETHA P	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 12/12/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/612,914	Hanna
Examiner	**Group Art Unit**
Geetha Bansal	

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 0 (30days) MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 7/10/00.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1-36 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claim(s) 1-36 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Action Summary

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6, drawn to antibody protein, classified in class 530, subclass 387.3.

II. Claims 7-11, drawn to nucleic acid encoding antibody, classified in class 536, subclass 23.53.

III. Claims 12-16, drawn to a method of expression and production of recombinant antibody protein, classified in class 435, subclass 320.1.

IV. Claims 17-36, drawn to a method of treatment or prevention of CD4 related conditions, classified in class 424, subclass .

2. The inventions are distinct, each from the other because of the following reasons: Inventions I, II, III and IV are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions differ from each other as follows:

A. Group I draws upon the making of a chimeric antibody molecule, which requires different methods and different reagents than the method of making of the nucleic acid of Group II. The products of Groups I and II are drawn to a different type of invention than the methods of Groups III and IV. Proteins (Group I) and nucleic acid(Group II) are structurally different molecules, and are therefore patentably distinct entities.

B. Group III is different from Groups I and II in that it constitutes a method of producing the recombinant antibody and as such requires a different set of methods and conditions, and thus is a patentably distinct invention. The inventions of Groups I and II are drawn to products.

C. Group IV is a method of treatment and is completely different from the method of Group III because the reagents and conditions required to achieve its endpoint different, and is a patentably distinct invention.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, different search requirements and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. This application contains claims directed to the following patentably distinct species of the claimed invention:

A. : wherein the human heavy constant domain is (claims 1, 2, 8, 18, 24, 30, 33) is:

1. gamma 1 isotype,
2. gamma 4 isotype or
3. mutated gamma 4 isotype.

These species are distinct because their structures and modes of action are different, which in turn addresses different functional end points.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

B. :wherein the anti-CD4 chimeric antibody (claims 1, 6, 11, 16, 21, 22, 27, 28, 35) is:

1. CE9.1
2. CE9γ4
3. CE9γ4λK
4. CE9γ4E or

5. CE9γ4PE.

These species are distinct because their structures and modes of action are different, which in turn addresses different functional end points.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1, 6 is generic.

C. : wherein the non-autoimmune disorder (claims 1-3, 17-19, 21, 32-36) is:

1. leukemia,
2. lymphoma,
3. graft-versus-host disease,
4. asthma,
5. transplant rejection or
6. HIV infection.

These species are distinct because their etiology and modes of disease operation are different, which in turn addresses different functional and therapeutic end points.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

5. Applicant is requested to elect one species from each of Groups A, B, and C.

6. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

8. Papers related to this application may be submitted to Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242 or (703) 305-3014.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Geetha P. Bansal whose telephone number is (703) 305-3955. The examiner can normally be reached on Mondays to Thursdays from 7:00am to 4:30pm and

alternate Fridays from 7:00am to 3:30pm. A message may be left on the examiner's voice mail service.

10. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Anthony Caputa, can be reached on (703) 308-3995.

11. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

September 2, 2001

GEETHA P. BANSAL
PRIMARY EXAMINER